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Fax Number: 571-273-8300 ; Examiner's Phone Number 571-272-0579

Note: As requested, enclosed is the APPEAL UNDER 37 CFR 1.192 re U.S. SN 10/010,678, filed 12/7/2001, Attorney's Docket No. 19109DE.

THIS MESSAGE IS FROM:

Name: Catherine D. Fitch

Phone No.: (732) 594-4283 Mail Location: **RY60-30**

Fax No.: (732) 594-4720

RE: U.S. Serial No.: 10/010,678
Filing Date: 12/7/2001
Attorney Docket No.: 19109DE
For: TRANSDERMAL TREATMENT WITH 5-ALPHA REDUCTASE INHIBITORS *(as amended)*

NUMBER OF PAGES BEING TRANSMITTED (INCLUDING COVER): 13

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	G.J. Gormley et al.		
Serial No.:	10/010,678	Case No.: 19109DE	Art Unit: 1618
Filed:	December 7, 2001		Examiner: V. Y. Kim
For:	TRANSDERMAL TREATMENT WITH 5-ALPHA-REDUCTASE INHIBITORS *(as amended)*		

Mail Stop: Appeal Brief-Patents
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Alexandria, VA 22313-1450

APPEAL UNDER 37 C.F.R. 1.192

Sir:

The present Brief is submitted in triplicate under the provisions of 37 C.F.R. 1.192 in support of an appeal from the May 6, 2005, rejection of Claims 28 to 37, which was maintained in the July 29, 2005, Advisory Action. The Notice of Appeal was timely filed August 5, 2005. Appellants hereby respectfully seek to have the rejections of Claims 28 to 37 overturned.

REAL PARTY IN INTEREST

The real party in interest is Merck & Co., Inc. of Rahway, New Jersey, by assignment recorded at the U.S. Patent and Trademark Office on April 26, 1996 (Reel 7916/Frame 0548). The inventors of the present application assigned their interests to Merck & Co., Inc., in an assignment executed April 25, 1994.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellants, or known to Appellants' legal representative, that will directly affect the Board's decision in the pending appeal, other than the earlier appeal in the present application, Appeal No. 2004-0543, decision mailed December 29, 2004.

STATUS OF CLAIMS

Claims pending: 28-37.
Claims cancelled: none.
Claims allowed: none.
Claims rejected: 28-37.
Claims on appeal: 28-37.

A complete copy of the Claims on appeal is provided in the accompanying Appendix.

STATUS OF AMENDMENTS

One preliminary amendment and two amendments were filed for this application. A preliminary amendment was filed on December 7, 2001, accompanying a new divisional application under 37 CFR 1.53(b) based on parent Application Serial No. 09/699,906. A second amendment under 37 CFR 1.111 was filed October 16, 2002. The two amendments were entered by the Examiner. Subsequently, A third amendment under 37 CFR 1.116 was filed April 25, 2003, (following a Final Office Action), but was never entered by the Examiner because the Examiner stated it raised new issues that would require further consideration and/or search. A Notice of Appeal was timely filed April 25, 2003, and a Decision on Appeal (Appeal No. 2004-0543) was mailed December 29, 2004. The Decision on Appeal raised a new ground of rejection under 37 CFR 41.50(b)(1), for which an amendment (the fourth) was timely filed January 27, 2005. The list of claims presented in Appendix I reflects entry of these amendments. A fifth

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SUMMARY OF THE INVENTION

The present invention as defined in Claims 28-32 under appeal relates to a method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. The invention defined in Claims 33-35 under appeal relates to a method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. The invention defined in Claims 36-37 under appeal relates to a transdermal skin patch comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor. A copy of the claims appears in Appendix I.

ISSUES

There is one issue being presented for review by the Board of Appeals. The issue on appeal is the rejection of Claims 28-37 under 35 U.S.C. § 103(a) as being unpatentable over Goldman, US 5,407,944. Appellants believe the rejection to be erroneous, as will be explained in the Argument Section below.

GROUPING OF CLAIMS

For the purpose of this Appeal, the Claims shall be grouped as follows:

Group I: Claims 28-29 and 31-34
Group II: Claims 30 and 35
Group III: Claims 36-37

The Claims of Groups I, II and III are considered to be separately patentable and do not stand or fall together. The Claims of Group I are directed to methods for treating androgenic

alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. The Claims of Group II are limited to methods of treating androgenic alopecia consisting essentially of transdermally admininistering to a person in need of such treatment a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, wherein the 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is transdermally administered by a transdermal skin patch. The Claims of Group III are directed to transdermal skin patches consisting essentially of a therapeutically effective amount of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as the active ingredient.

ARGUMENT

As set forth in detail below, Appellants submit that the methods for treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as defined by Claims 28, 29 and 31-34, the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, in a transdermal skin patch, as defined by Claims 30 and 35, and the transdermal skin patch consisting essentially of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient as defined by Claims 36 and 37, are nonobvious over the cited references. Applicants submit that the Board of Appeals should reverse the Examiner's rejections of Claims 28-37. Favorable action by the Board is respectfully requested.

Issue: Claims 28 to 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman (US 54079444).

The Examiner's Rationale

Claims 28 to 37 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Goldman (US 5,407,944). On pages 2-3 of the office action dated May 6, 2005, the Examiner stated:

> Claim 28 is directed to a method of treating androgenic alopecia consisting essentially of transversally [sic] administering to a person in need of such treatment a therapeutically effective amount of a 5 α-reductase 2 inhibitor; Claim 30 specifies administration by transferal skin patch [sic]; Claim 33 specifies that the 5 α-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)4-aza-5 α-androst-1-ene-3-one), otherwise known as a "Finasteride"; Claim 36 is directed to a skin patch consisting essentially of a 5 α-reductase 2 inhibitor.
>
> Goldman (US'944, hereinafter) teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and a 5 α-reductase inhibitor (Column 2, lines 42-46; Column 6, lines 5-9), "A higly [sic] preferred inhibitor or ... 5 α-reductase for use in [Goldman's] compositions and methods" (Column 5, lines 43-44), indeed the only 5-α-reductase inhibitor specifically mentioned, is finasteride (Column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner" (Column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transderma patches or preparation" (Column 3, lines 7-10).
>
> While Goldman does not specifically describe incorporating a 5 α-reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preffered [sic]" 5 α-reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, consisting essentially of a 5 α-reductase inhibitor, e.g., finasteride, in view of Goldman's explicit suggestions.

"Consisting Essentially Of"

Applicants amend the claims and argues that the pending Claims 28-37 are patentably distinguish [sic] over Goldman in view of the transition phrase "consisting essentially of" (Request for reconsideration and withdrawal of the rejection, see Remark section at page 6, filed 1/31/05). According to applicants, the recitation of an active component in those claims "consisting essentially of" 5 α-reductase inhibitor (Claims 28-32) or finasteride (Claims 33-37) exclude a vasodilator or an estradiol disclosed by Goldman.

The examiner disagree [sic].

As stated in PPG Indus., Inc. v. Guardian Indus. Corp., 156 F.3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354 (Fed. Cir. 1998),

> By using the term "consisting essentially of", the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format. (Emphasis added).

Here applicants' argument that "consisting essentially of" excludes those vasodilator or estradiols of Goldman is an example of idse dixit reasoning. Applicants do not describe the "basic and novel properties of the invention", or explain why or establish how the vasodilators or estradiols of Goldman materially affects those properties.

Additionally, it is apparent from applicant's specification (page 7-9) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the vasodilators or estradiols of Goldman would "materially affect" the basic and novel properties of the invention and, accordingly, be excluded by the phrase "consisting essentially of", whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase "consisting essentially of". Applicants have not made it

clear, in their specification or in their request for reconsideration, what they "regarded as constituting a material change in the c the basic and novel properties of the invention" [sic].

I. The § 103 (a) Obviousness Rejection of Claims 28,29 and 31-34 over Goldman et al. is Improper

Claims 28, 29 and 31-34 specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents. These active agents are selected from vasodilators, estradiols, 5alpha-reductase inhibitors and salts, esters and prodrugs thereof. Goldman does not teach or even suggest the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha reductase inhibitor. Indeed, in the only exemplification in Goldman, the 5alpha-reductase inhibitor is used in prophetic examples (1) with a vasodilator and estradiol, in a 3 ingredient treatment (US 5,407,944 col. 8, line 68-col. 9, line 2) and (2) with a vasodilator and a 5alpha-reductase inhibitor in a 2 ingredient combination (Ibid., col. 9, lines 3-4).

Contrary to the Examiner's contention, the expression "consisting essentially of" does not permit additional active ingredients, such as vasodilators and estradiol. Consisting essentially of excludes other elements from having any essential significance to the combination. The additional ingredients in Goldman useful for growing hair are elements that would have essential significance in the combination. "Consisting essentially of" permits a degree of "reading on" additional unspecified substances which do not affect the basic and novel characteristics of the claimed invention. See, Practicing Law Institute, Landis On Mechanics of Patent Claim Drafting, 1997, § 8. However, additional active ingredients do affect the basic characteristics of the claimed invention and are not encompassed by the presently drafted claims.

II. The § 103 (a) Obviousness Rejection of Claims 30 and 35 over Goldman et al. is Improper

Claims 30 and 35 depend from Claims 28 and 31, respectively, and add the limitation that the 5a-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. Goldman does not teach or suggest administration of a

5alpha-reductase inhibitor via transdermal patch. Goldman does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);
(2) Minoxidil in tablet form (col. 3, lines 53-62);
(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the Goldman patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the Goldman patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The Goldman patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations Goldman teaches in the patent, Goldman teaches away from the administration of a 5alpha-reductase inhibitor via transdermal skin patch.

III. The § 103 (a) Obviousness Rejection of Claims 36 and 37 over Goldman et al. is Improper

Claims 36 and 37 are directed to a transdermal skin patch consisting essentially of a 5alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient. Goldman does not teach or suggest a transdermal skin patch consisting essentially of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

Claims 30 and 35 depend from Claims 28 and 31, respectively, and add the limitation that the 5a-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. Goldman does not teach or suggest administration of a

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(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

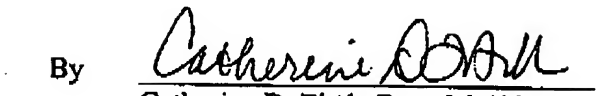
Of the nine formulations listed above from the Goldman patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the Goldman patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The Goldman patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations Goldman teaches in the patent (cited above), Goldman teaches away from the a transdermal skin patch consisting essentially of a 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

SUMMARY

For the foregoing reasons, Appellants maintain that the Goldman reference of record does not render obvious the invention as claimed in Claims 28-37 in the subject application. Moreover, each of the groups of claims should not stand or fall together. The Board of Patent Appeals and Interferences is respectfully requested to overturn the Examiner's rejections and to

allow Claims 28-37.

Respectfully submitted,

By 

Catherine D. Fitch, Reg. 36,502
Attorney for Applicants

MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065

Date: October 5, 2005
Submitted in triplicate

APPENDIX I

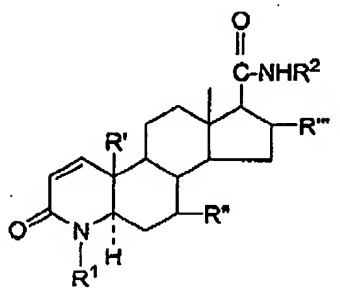
The claims on appeal are as follows:

Claim 28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

Claim 29. The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

Claim 30. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

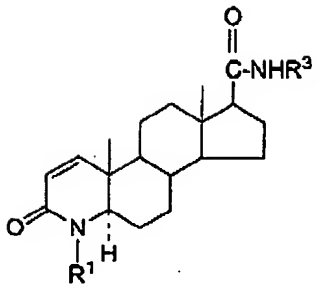
Claim 31. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:
R^1 is hydrogen, methyl or ethyl;
R^2 is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen substituents selected from Cl, F and Br;
R' is hydrogen or methyl;
R" is hydrogen or β-methyl; and
R''' is hydrogen, α-methyl or β-methyl.

Claim 32. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:
R^1 is hydrogen or methyl; and
R^3 is branched chain alkyl of from 4 to 8 carbons.

Claim 33. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

Claim 34. The method of Claim 33 wherein androgen alopecia is male pattern baldness.

Claim 35. The method according to Claim 33, wherein the 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

Claim 36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

Claim 37. The transdermal skin patch according to Claim 36 wherein the 5alpha-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

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As set forth in detail below, Appellants submit that the methods for treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as defined by Claims 28, 29 and 31-34, the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, in a transdermal skin patch, as defined by Claims 30 and 35, and the transdermal skin patch consisting essentially of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient as defined by Claims 36 and 37, are nonobvious over the cited references. Applicants submit that the Board of Appeals should reverse the Examiner's rejections of Claims 28-37. Favorable action by the Board is respectfully requested.

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>
> Goldman (US'944, hereinafter) teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and a 5 α-reductase inhibitor (Column 2, lines 42-46; Column 6, lines 5-9), "A higly [sic] preferred inhibitor or ... 5 α-reductase for use in [Goldman's] compositions and methods" (Column 5, lines 43-44), indeed the only 5-α-reductase inhibitor specifically mentioned, is finasteride (Column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner" (Column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transderma patches or preparation" (Column 3, lines 7-10).
>
> While Goldman does not specifically describe incorporating a 5 α-reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preffered [sic]" 5 α-reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, consisting essentially of a 5 α-reductase inhibitor, e.g., finasteride, in view of Goldman's explicit suggestions.

"Consisting Essentially Of"

Applicants amend the claims and argues that the pending Claims 28-37 are patentably distinguish [sic] over Goldman in view of the transition phrase "consisting essentially of" (Request for reconsideration and withdrawal of the rejection, see Remark section at page 6, filed 1/31/05). According to applicants, the recitation of an active component in those claims "consisting essentially of" 5 α-reductase inhibitor (Claims 28-32) or finasteride (Claims 33-37) exclude a vasodilator or an estradiol disclosed by Goldman.

The examiner disagree [sic].

As stated in PPG Indus., Inc. v. Guardian Indus. Corp., 156 F.3d 1351, 1355, 48 USPQ 2d 1351, 1353-1354 (Fed. Cir. 1998),

> By using the term "consisting essentially of", the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully open claims that are drafted in a "comprising" format. (Emphasis added).

Here applicants' argument that "consisting essentially of" excludes those vasodilator or estradiols of Goldman is an example of idse dixit reasoning. Applicants do not describe the "basic and novel properties of the invention", or explain why or establish how the vasodilators or estradiols of Goldman materially affects those properties.

Additionally, it is apparent from applicant's specification (page 7-9) that the composition of the claimed method may include a host of ingredients or additives. On this record, it is unclear why the vasodilators or estradiols of Goldman would "materially affect" the basic and novel properties of the invention and, accordingly, be excluded by the phrase "consisting essentially of", whereas the host of ingredients listed in the specification do not materially affect the basic and novel properties of the invention and, accordingly, are included by the phrase "consisting essentially of". Applicants have not made it

clear, in their specification or in their request for reconsideration, what they "regarded as constituting a material change in the c the basic and novel properties of the invention" [sic].

I. The § 103 (a) Obviousness Rejection of Claims 28,29 and 31-34 over Goldman et al. is Improper

Claims 28, 29 and 31-34 specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents. These active agents are selected from vasodilators, estradiols, 5alpha-reductase inhibitors and salts, esters and prodrugs thereof. Goldman does not teach or even suggest the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha reductase inhibitor. Indeed, in the only exemplification in Goldman, the 5alpha-reductase inhibitor is used in prophetic examples (1) with a vasodilator and estradiol, in a 3 ingredient treatment (US 5,407,944 col. 8, line 68-col. 9, line 2) and (2) with a vasodilator and a 5alpha-reductase inhibitor in a 2 ingredient combination (Ibid., col. 9, lines 3-4).

Contrary to the Examiner's contention, the expression "consisting essentially of" does not permit additional active ingredients, such as vasodilators and estradiol. Consisting essentially of excludes other elements from having any essential significance to the combination. The additional ingredients in Goldman useful for growing hair are elements that would have essential significance in the combination. "Consisting essentially of" permits a degree of "reading on" additional unspecified substances which do not affect the basic and novel characteristics of the claimed invention. See, Practicing Law Institute, Landis On Mechanics of Patent Claim Drafting, 1997, § 8. However, additional active ingredients do affect the basic characteristics of the claimed invention and are not encompassed by the presently drafted claims.

II. The § 103 (a) Obviousness Rejection of Claims 30 and 35 over Goldman et al. is Improper

Claims 30 and 35 depend from Claims 28 and 31, respectively, and add the limitation that the 5a-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. Goldman does not teach or suggest administration of a

5alpha-reductase inhibitor via transdermal patch. Goldman does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);
(2) Minoxidil in tablet form (col. 3, lines 53-62);
(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the Goldman patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the Goldman patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The Goldman patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations Goldman teaches in the patent, Goldman teaches away from the administration of a 5alpha-reductase inhibitor via transdermal skin patch.

III. The § 103 (a) Obviousness Rejection of Claims 36 and 37 over Goldman et al. is Improper

Claims 36 and 37 are directed to a transdermal skin patch consisting essentially of a 5alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient. Goldman does not teach or suggest a transdermal skin patch consisting essentially of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

Claims 30 and 35 depend from Claims 28 and 31, respectively, and add the limitation that the 5a-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. Goldman does not teach or suggest administration of a

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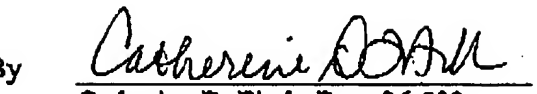
SUMMARY

For the foregoing reasons, Appellants maintain that the Goldman reference of record does not render obvious the invention as claimed in Claims 28-37 in the subject application. Moreover, each of the groups of claims should not stand or fall together. The Board of Patent Appeals and Interferences is respectfully requested to overturn the Examiner's rejections and to

allow Claims 28-37.

Respectfully submitted,

By 

Catherine D. Fitch, Reg. 36,502
Attorney for Applicants

MERCK & CO., Inc.
P.O. Box 2000
Rahway, New Jersey 07065

Date: October 5, 2005
Submitted in triplicate

APPENDIX I

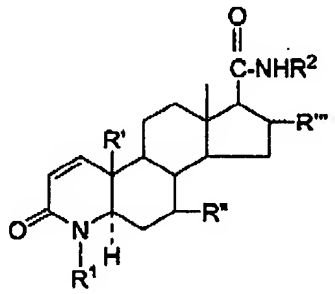
The claims on appeal are as follows:

Claim 28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

Claim 29. The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

Claim 30. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

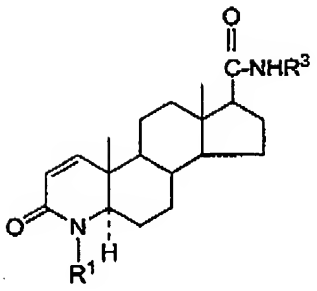
Claim 31. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:
R^1 is hydrogen, methyl or ethyl;
R^2 is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen substituents selected from Cl, F and Br;
R' is hydrogen or methyl;
R" is hydrogen or β-methyl; and
R''' is hydrogen, α-methyl or β-methyl.

Claim 32. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:
R^1 is hydrogen or methyl; and
R^3 is branched chain alkyl of from 4 to 8 carbons.

Claim 33. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

Claim 34. The method of Claim 33 wherein androgen alopecia is male pattern baldness.

Claim 35. The method according to Claim 33, wherein the 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

Claim 36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

Claim 37. The transdermal skin patch according to Claim 36 wherein the 5alpha-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	G.J. Gormley et al.		
Serial No.:	10/010,678	Case No.: 19109DE	Art Unit: 1618
Filed:	December 7, 2001		Examiner: V. Y. Kim
For:	TRANSDERMAL TREATMENT WITH 5-ALPHA-REDUCTASE INHIBITORS *(as amended)*		

Mail Stop: Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL UNDER 37 C.F.R. 1.192

Sir:

The present Brief is submitted in triplicate under the provisions of 37 C.F.R. 1.192 in support of an appeal from the May 6, 2005, rejection of Claims 28 to 37, which was maintained in the July 29, 2005, Advisory Action. The Notice of Appeal was timely filed August 5, 2005. Appellants hereby respectfully seek to have the rejections of Claims 28 to 37 overturned.

REAL PARTY IN INTEREST

The real party in interest is Merck & Co., Inc. of Rahway, New Jersey, by assignment recorded at the U.S. Patent and Trademark Office on April 26, 1996 (Reel 7916/Frame 0548). The inventors of the present application assigned their interests to Merck & Co., Inc., in an assignment executed April 25, 1994.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellants, or known to Appellants' legal representative, that will directly affect the Board's decision in the pending appeal, other than the earlier appeal in the present application, Appeal No. 2004-0543, decision mailed December 29, 2004.

STATUS OF CLAIMS

Claims pending: 28-37.
Claims cancelled: none.
Claims allowed: none.
Claims rejected: 28-37.
Claims on appeal: 28-37.

A complete copy of the Claims on appeal is provided in the accompanying Appendix.

STATUS OF AMENDMENTS

One preliminary amendment and two amendments were filed for this application. A preliminary amendment was filed on December 7, 2001, accompanying a new divisional application under 37 CFR 1.53(b) based on parent Application Serial No. 09/699,906. A second amendment under 37 CFR 1.111 was filed October 16, 2002. The two amendments were entered by the Examiner. Subsequently, A third amendment under 37 CFR 1.116 was filed April 25, 2003, (following a Final Office Action), but was never entered by the Examiner because the Examiner stated it raised new issues that would require further consideration and/or search. A Notice of Appeal was timely filed April 25, 2003, and a Decision on Appeal (Appeal No. 2004-0543) was mailed December 29, 2004. The Decision on Appeal raised a new ground of rejection under 37 CFR 41.50(b)(1), for which an amendment (the fourth) was timely filed January 27, 2005. The list of claims presented in Appendix I reflects entry of these amendments. A fifth

amendment under 37 CFR 1.116 was filed June 24, 2005, in response to the May 6, 2005, final rejection. These amendments were not entered as the Examiner contended they raised new issues requiring further consideration and/or search, because the claims were narrowed and could require a new search.

SUMMARY OF THE INVENTION

The present invention as defined in Claims 28-32 under appeal relates to a method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. The invention defined in Claims 33-35 under appeal relates to a method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. The invention defined in Claims 36-37 under appeal relates to a transdermal skin patch comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor. A copy of the claims appears in Appendix I.

ISSUES

There is one issue being presented for review by the Board of Appeals. The issue on appeal is the rejection of Claims 28-37 under 35 U.S.C. § 103(a) as being unpatentable over Goldman, US 5,407,944. Appellants believe the rejection to be erroneous, as will be explained in the Argument Section below.

GROUPING OF CLAIMS

For the purpose of this Appeal, the Claims shall be grouped as follows:

Group I: Claims 28-29 and 31-34
Group II: Claims 30 and 35
Group III: Claims 36-37

The Claims of Groups I, II and III are considered to be separately patentable and do not stand or fall together. The Claims of Group I are directed to methods for treating androgenic

alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. The Claims of Group II are limited to methods of treating androgenic alopecia consisting essentially of transdermally admininistering to a person in need of such treatment a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, wherein the 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is transdermally administered by a transdermal skin patch. The Claims of Group III are directed to transdermal skin patches consisting essentially of a therapeutically effective amount of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as the active ingredient.

ARGUMENT

As set forth in detail below, Appellants submit that the methods for treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as defined by Claims 28, 29 and 31-34, the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, in a transdermal skin patch, as defined by Claims 30 and 35, and the transdermal skin patch consisting essentially of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient as defined by Claims 36 and 37, are nonobvious over the cited references. Applicants submit that the Board of Appeals should reverse the Examiner's rejections of Claims 28-37. Favorable action by the Board is respectfully requested.

Issue: Claims 28 to 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goldman (US 54079444).

The Examiner's Rationale

Claims 28 to 37 were rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Goldman (US 5,407,944). On pages 2-3 of the office action dated May 6, 2005, the Examiner stated:

> Claim 28 is directed to a method of treating androgenic alopecia consisting essentially of transversally [sic] administering to a person in need of such treatment a therapeutically effective amount of a 5 α-reductase 2 inhibitor; Claim 30 specifies administration by transferal skin patch [sic]; Claim 33 specifies that the 5 α-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)4-aza-5 α-androst-1-ene-3-one), otherwise known as a "Finasteride"; Claim 36 is directed to a skin patch consisting essentially of a 5 α-reductase 2 inhibitor.
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"Consisting Essentially Of"

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(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

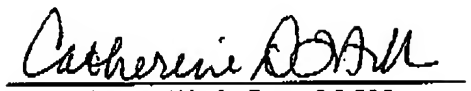
Of the nine formulations listed above from the Goldman patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the Goldman patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The Goldman patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations Goldman teaches in the patent (cited above), Goldman teaches away from the a transdermal skin patch consisting essentially of a 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

SUMMARY

For the foregoing reasons, Appellants maintain that the Goldman reference of record does not render obvious the invention as claimed in Claims 28-37 in the subject application. Moreover, each of the groups of claims should not stand or fall together. The Board of Patent Appeals and Interferences is respectfully requested to overturn the Examiner's rejections and to

allow Claims 28-37.

Respectfully submitted,

By 

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Date: October 5, 2005
Submitted in triplicate

APPENDIX I

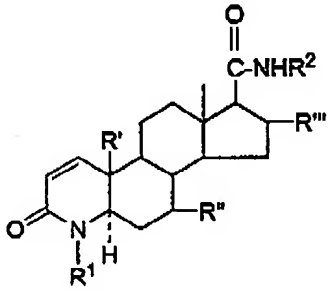
The claims on appeal are as follows:

Claim 28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

Claim 29. The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

Claim 30. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

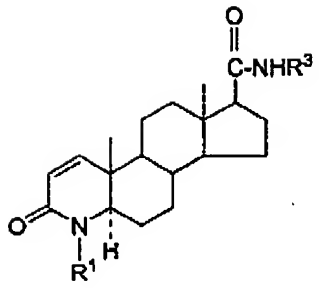
Claim 31. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:
R^1 is hydrogen, methyl or ethyl;
R^2 is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen substituents selected from Cl, F and Br;
R' is hydrogen or methyl;
R" is hydrogen or β-methyl; and
R''' is hydrogen, α-methyl or β-methyl.

Claim 32. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:
R^1 is hydrogen or methyl; and
R^3 is branched chain alkyl of from 4 to 8 carbons.

Claim 33. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

Claim 34. The method of Claim 33 wherein androgen alopecia is male pattern baldness.

Claim 35. The method according to Claim 33, wherein the 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

Claim 36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

Claim 37. The transdermal skin patch according to Claim 36 wherein the 5alpha-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.